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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,329	10/28/2003	David Schneider	SDR-10802/01	4848

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EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,329	SCHNEIDER, DAVID	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-16 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-16 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 1/8/2008. Claims 1 and 11 are amended. Claims 4 and 17 are cancelled. **Claims 1-3, 5-16, and 18-22** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1-3, 5, 9-16, 18, and 21-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (WO 9802249) or Fitzgerald et al (US Pub No. 20030054012) in view of D'Angelo (US Pat No. 5910122), further in view of Thieme et al (5871905).

4. In regards to **Claim 1**, Cunningham or Fitzgerald et al disclose collecting a saliva sample for subsequent assay of a biologic therein using a saliva collection device consisting of a transfer pipette, which necessarily has a compression end and an intake end. See Cunningham p.10 line 11-12; p.19 line 5-6. Also see Fitzgerald et al ¶0262, 0273. However, Cunningham or Fitzgerald et al do not explicitly disclose a kit for the collection and preservation of the saliva sample comprising a container and a salivation catalyst positioned directly on the intake end of the saliva collection device.

5. D'Angelo discloses a kit for the collection and preservation of a saliva sample comprising a container 10 and a saliva collection device, best seen in Figure 3-9, to effectively store the saliva sample after collection. D'Angelo also teaches that it is well known within the art to position a salivation catalyst (Col.5: 3-5) directly on the exterior surface 1 of the saliva collection device, best seen in Figure 1-2, to effectively stimulate a patient's saliva production for collection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cunningham or Fitzgerald et al to include a container and a salivation catalyst positioned directly on the saliva collection device, i.e. the intake end, as taught by D'Angelo, to effectively store the saliva sample after collection and to effectively stimulate a patient's saliva production for adequate collection.

6. However, Cunningham or Fitzgerald et al in combination with D'Angelo do not disclose a preservative solution retained within said container. Thieme et al teaches that it is well known within the art to provide a kit for the collection and preservation of a saliva sample comprising a container with a preservation solution retained within said container to maintain the integrity and prevent contamination of the sample during transportation before analysis (Col.11: 39-45). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cunningham or Fitzgerald et al as modified by D'Angelo above to include a preservative solution within a container, as taught by Thieme et al, to maintain the integrity and prevent contamination of the sample during transportation before analysis.

7. In regards to **Claim 2**, D'Angelo discloses the container 10 comprises a resealable tube.

8. In regards to **Claim 3**, D'Angelo discloses the resealable tube comprises a polyethylene transfer vial (Col.5: 43-45).

9. In regards to **Claim 5**, D'Angelo discloses the salivation catalyst comprises a food flavoring (Col.5: 3-5).

10. In regard to **Claims 9-10**, Thieme et al disclose the preservative solution comprises a fungicide and a bactericide (Col.5: 65-68).

11. In regards to **Claim 11**, Cunningham or Fitzgerald et al disclose a method of assaying for a biologic comprising the steps of: providing a saliva collection device consisting of a transfer pipette, which necessarily has a compression end and an intake end, wherein collection at a first location of a saliva sample directly from a mouth of a user is thus performed by placing the intake end of the transfer pipette into a user's mouth and drawing a fluid saliva sample into the intake end of the transfer pipette. See Cunningham p.10 line 11-12; p.19 line 5-6. Also see Fitzgerald et al ¶0262, 0273. However, Cunningham or Fitzgerald et al do not explicitly disclose the steps of providing a container with a preservative solution within the container.

12. Thieme et al disclose a method of assaying for a biologic comprising the steps of: providing a container (Col.11: 39-45); providing a preservative solution within the container (Col.11: 39-45); providing a saliva collection device, best seen in Figures 1A and 1B; collecting at a first location a saliva sample directly from a mouth of a user using the saliva collection device (Col.11: 22-33); depositing the saliva sample into the container (Col.11: 34-35); and sealing the container having the saliva sample against spillage and tampering (Col.11: 39-59).

13. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Cunningham or Fitzgerald et al to include the method steps above including providing a container and depositing the saliva sample along with the saliva collection device into the container and sealing it as taught by Thieme et al as an effective method to collect and subsequently preserve the saliva sample for assay of a biologic. However, Cunningham or Fitzgerald et al in combination with Thieme et al do not disclose the saliva collection device has a salivation catalyst positioned directly on the intake end.

14. D'Angelo teach that it is well known within the art to position a salivation catalyst (Col.5: 3-5) directly on the exterior surface 1 of the saliva collection device, best seen in Figure 1-2, to effectively stimulate a patient's saliva production for collection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Cunningham or Fitzgerald et al as modified by Thieme et al above to include a salivation catalyst positioned directly on the saliva collection device, i.e. the intake end, as taught by D'Angelo, to effectively stimulate a patient's saliva production for adequate collection.

15. In regard to **Claims 12-14**, Thieme et al disclose shipping the container having the saliva collection device to a second location and assaying the saliva sample and preservative solution for a biologic at the second location (Col.11: 46-51; Col.12: 4-9).

16. In regards to **Claim 15**, Cunningham or Fitzgerald et al in combination with Thieme et al and D'Angelo disclose the claimed method except for the container comprising a resealable tube. D'Angelo teaches that it is known to provide a resealable tube 10 to allow for reopening and

closing of the tube to perform multiple analyses on the sample as well as other functional use. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Cunningham or Fitzgerald as modified by Thieme et al and D'Angelo to include a resealable container, as taught by D'Angelo, to allow for reopening and closing of the tube to perform multiple analyses on the sample and other functional uses.

17. In regards to **Claim 16**, D'Angelo discloses the resealable tube comprises a polyethylene transfer vial (Col.5: 43-45).

18. In regards to **Claim 18**, D'Angelo discloses the salivation catalyst comprises a food flavoring (Col.5: 3-5).

19. In regard to **Claims 21-22**, Thieme et al disclose the preservative solution comprises a fungicide and a bactericide (Col.5: 65-68).

20. **Claims 6 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham or Fitzgerald in view of D'Angelo and Thieme et al, further in view of Aronowitz (US Pat No. 20010008614).

21. Cunningham or Fitzgerald et al in combination with D'Angelo and Thieme et al disclose the invention above including a food flavoring salivation catalyst but do not disclose the flavoring being selected from a group consisting of lemon, peppermint, spearmint and orange flavorings. Aronowitz teaches it is well known in the art to provide a flavoring that includes

lemon, lime, orange or the like (¶0017) to stimulate a person's saliva production. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Cunningham or Fitzgerald et al as modified by D'Angelo and Thieme et al in the manner above such that the flavoring is selected from a group consisting of lemon, peppermint, spearmint and orange flavorings, as taught by Aronowitz, to effectively stimulate saliva production.

22. **Claims 7-8 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham or Fitzgerald et al in combination with D'Angelo and Thieme et al, further in view of Putcha et al (US Pat No. 6133036).

23. Cunningham or Fitzgerald et al in combination with D'Angelo and Thieme et al disclose the claimed invention above except for the preservative solution comprising: sodium chloride, $NaHPO_4$ and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and 0.5-2.0 g sodium benzoate. However, it is noted that applicant provides two other preservative solutions that can also be used in the same application and device on p.12 of the specification. Therefore the solution is deemed not to be a critical component of the current application and at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a preservative solution of sodium chloride, $NaHPO_4$ and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. Applicant has not disclosed the specifics of the solution providing an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected applicant's invention to perform equally as well

with either the solution taught by Putcha et al or the claimed solution because both solutions would perform the same function of preserving the collected sample equally well. Therefore, it would have been prima facie obvious to further modify the invention of Cunningham or Fitzgerald et al as modified by D'Angelo and Thieme et al above to obtain the invention as specified in claims 7-8 and 20 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Putcha et al.

Response to Arguments

24. Applicant's arguments with respect to claims 1-3, 5-16, and 18-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736